



Patent
Attorney's Docket No. 032781-003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
Stanley Mandel et al.)	Group Art Unit: 3765
Application No.: 09/864,585)	Examiner: Amy B. Vanatta
Filed: May 24, 2001)	Confirmation No.: 2107
For: Surface Treated Ligating Clip)	

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RESPONSE UNDER 37 C.F.R. § 1.111

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In complete response to the Office Action mailed September 11, 2002, Applicants respectfully request reconsideration of the claims in view of the following remarks.

Claims 1-27 are pending in the application. Claims 5-11, 16 and 19-26 were withdrawn from examination pursuant to a restriction/election requirement. Claims 1-4, 12-15, 17-18 and 27 have been examined. Applicants appreciate the Examiner renumbering the last claim to be in accordance with 37 C.F.R. § 1.126.

Applicants were required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits from the following groups:

Species of the device: I. clip
II. clip applier

Species of the material: A. metal
B. polymer

Species of the antimicrobial or antibiotic composition: I. coating
II. incorporated into the material of the device

Applicants hereby confirm the provisional election without traverse of the invention of the clip, the polymer and the coating, embodied by claims 1-4, 12-15, 17, 18 and 27 (as amended). Applicants reserve the right to file a divisional application to the claims withdrawn from examination pursuant to the restriction/election requirement.

Claims 1, 2, 12, 15 and 18 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kuehn et al., U.S. Patent No. 6,165,183. Applicants respectfully traverse this rejection.

Independent claim 1 is directed to a polymeric ligating clip for use in a body having one or more surfaces coated with an antimicrobial or antibiotic coating composition. Independent claim 12 is directed to a method for inhibiting the growth of or killing microorganisms comprising coating a ligating clip or a ligating clip applying instrument with an antimicrobial or antibiotic coating composition. Ligating clips are used to ligate vessels or tissue bundles to stop the flow of blood. The clips may be left in place permanently or may be absorbable. *Paragraph 0002*.

Kuehn et al. does not disclose each and every feature of the claimed invention. Kuehn et al. relates to mitral and tricuspid valve repair. The device described functions as a connector mechanism, not as a ligation device. The purpose and context of use of the device in Kuehn et al. differs such that the claims directed to ligating clips and methods for inhibiting the growth of or killing microorganisms comprising coating a ligating clip are not anticipated thereby.

Moreover, Kuehn et al. would not have made the claimed invention obvious to one of skill in the art. The device described in Kuehn et al. is intended for use during a particular type of operation. The ligating clip and methods defined by the rejected claims, in contrast, are for use in the body for ligation of vessels or tissue bundles to stop the flow of blood. The coatings have been proven to terminate microorganisms in a variety of ways, depending on the type of coating used or the ability of the antimicrobial and/or antibiotic materials to be included. *See, for example, paragraph 0034*. As noted in the specification, previously known clips may provide opportunities for infection in the patient since infectious organisms may enter the body from a contaminated or infected surgical field or may be already present in the body. *Paragraph 0006*. Thus, the requirements of a ligating clip differ from the devices described in Kuehn et al. and one of skill in the art would not have used the teachings of Kuehn et al. in a ligating clip or methods as claimed. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 1-4, 12-15, 17, 18 and 27 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fox et al., U.S. Patent No. 5,019,096. Applicants respectfully traverse this rejection.

Fox et al. describes methods of preparing an infection-resistant medical device. According to Fox et al., medical devices are those for use both externally and internally and include, for example, urinary, both internal and external, and intravenous catheters, contraceptives such as condoms, medical gloves, such as surgical and examination gloves,

wound dressings, drainage tubes, orthopedic, penile and other implants, wound clips, sutures, hernia patches and arterial grafts. *Column 3, lines 9-16.* Fox et al. does not disclose each and every feature of the rejected claims as it does not describe a ligating clip. In view thereof, the rejected claims are not anticipated by Fox et al.

Moreover, the invention as defined by the rejected claims would not have been obvious to one of skill in the art in view of the differing structures and usages of the medical devices as described by Fox et al. and the structure and use of ligating clips. As discussed above, ligating clips are used to ligate vessels or tissue bundles to stop the flow of blood. The clips may be left in place permanently or may be absorbable. Such clips are used before the vessel is transected. A wound clip is used on a incision or bodily injury while the ligating clip is used to prevent bleeding prior to injury or incision.

In view of these differences between the invention as defined in the rejected claims and the disclosure of Fox et al., Applicants respectfully request that this rejection be withdrawn.

Further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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